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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,043	02/17/2004	Elizabeth Bates	SF0977XB	1489

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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KENILWORTH, NJ 07033-0530

EXAMINER

CROWDER, CHUN

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/780,043

Applicant(s)

BATES ET AL.

Examiner

Chun Crowder

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/28/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,9 and 17-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 9, 17-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment, filed 04/28/2006, is acknowledged.

Claims 1-6, 8 and 10-16 have been canceled.

Claim 7 has been amended.

Claims 17-30 have been added.

Claims 7, 9, 17-30 are pending and currently under consideration.

2. This Office Action will be in response to applicant's arguments, filed 04/28/2006.

The rejections of record can be found in the previous Office Action, mailed 02/22/2006.

The text of those sections of Title 35 U.S.C. not included in this Action can be found in a prior Action.

3. Applicant's IDS, filed 04/28/2006 is acknowledged and has been considered.

4. Claim 9 is rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 9 is indefinite in that it depends on canceled claim 8. Applicant should amend the claim as independent from the canceled claims.

For examination purposes, claim 9 reads as a dependent on claim 7.

B) Claim 18 is indefinite in the recitation of “antibody half molecule” because the phrase fails to point out and distinctly claim the subject matter of the claimed invention with identifying characteristics.

C) Claims 24 and 30 are indefinite in the recitation of “a unit dose” because the metes and bounds of the “unit dose” are unclear and ambiguous. It is not clear what “a unit dose” encompasses and one of ordinary skill in the art would not be reasonable apprised of the metes and bounds of the invention.

D) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

5. Claims 7, 9, 17-30 are rejected under **35 U.S.C. 102(b)** as being anticipated by Adema et al. (WO 98/24906, cited in IDS filed 02/17/04) (see entire document) as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886) for reasons of record set forth in the previous Office Action.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that Adema et al. do not disclose the polypeptide consisting amino acid sequence of SEQ ID NO:6, therefore, Adema et al. fail to inherently disclose an antibody or fragment thereof that specifically binds to an isolated polypeptide consisting of the amino acid sequence of SEQ ID NO:6. Applicant further argues that Bost et al. and Bendayan do not establish that an antibody that binds specifically to polypeptide of SEQ ID NO:2 of Adema et al. would necessarily bind specifically to the instant claimed polypeptide of SEQ ID NO:6.

This is not found persuasive for following reasons:

Contrary to applicant's arguments, the polypeptide having the amino acid sequences of SEQ ID NO:2 taught by Adema et al. is 80.4% identical to the claimed polypeptide of SEQ ID NO:6. In addition, both the prior art and the instant polypeptides are isolated from monocytes (see entire document, particularly Summary of Invention on pages 2-4). Further, Adema et al. teach methods of making and using antibodies using polypeptide having amino acid sequences of SEQ ID NO:2 as immunogen using techniques such as hybridoma and recombinant technology.

Furthermore, Adema et al. teach that the antibody can be fragment such as Fab, Fv, and can be attached to solid support including beads, and be included in units such as a kit (e.g. see pages 4-6). Moreover, Adema et al. teach that the antibody can be formulated into a pharmaceutical composition with pharmaceutically acceptable carriers for parenteral administrations (e.g. see page 4 and 22-45).

The teachings of Bost et al. and Bendayan provide technical reasoning to support the determination that antibody binding of distinct proteins was indeed specific.

Although the reference is silent about the antibody binding to SEQ ID NO: 6, it does not mean that the reference antibody does not bind to these sequences, especially given the high homology shared between the prior art polypeptide and the instant polypeptide. Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibodies do not bind to polypeptide consisting amino acid sequence of SEQ ID NO:6 recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980); MPEP 2112.01.

Therefore the prior art antibody anticipate the claimed invention.

The rejection or record is maintained for the reasons of record, as it applies to the amended claims. The rejection of record is incorporated by reference herein as if reiterated in full.

6. Upon further consideration as well as applicant's amendment, the previous rejections under **35 U.S.C. 112, first and second paragraphs** have been withdrawn.

7. ***Conclusion: no claim is allowed.***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.

Patent Examiner

June 30, 2006

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PRIMARY EXAMINER
TZ600
7/6/06